SIGMA 6000+
PROGRAMMABLE INFUSION PUMP

Operator's Manual
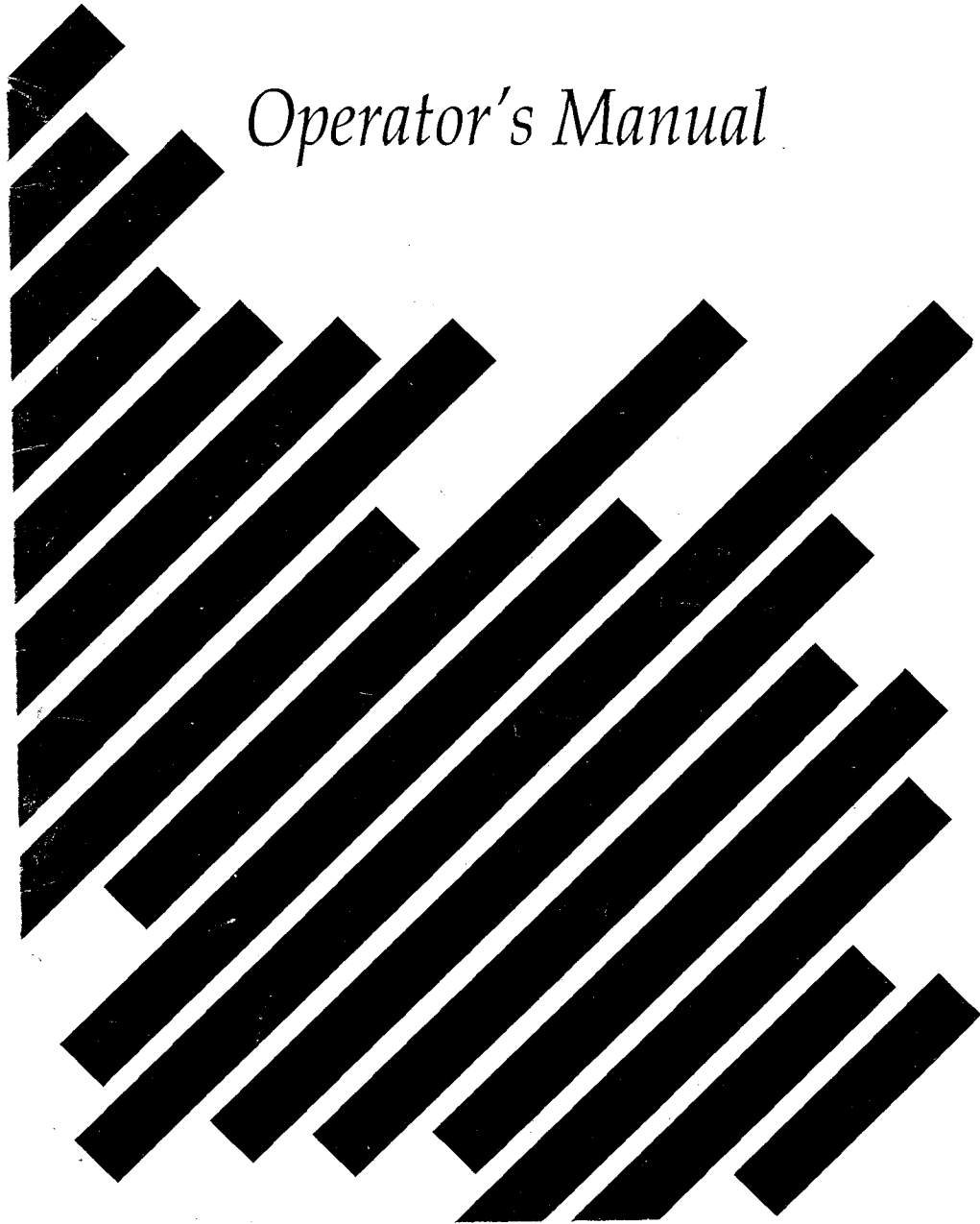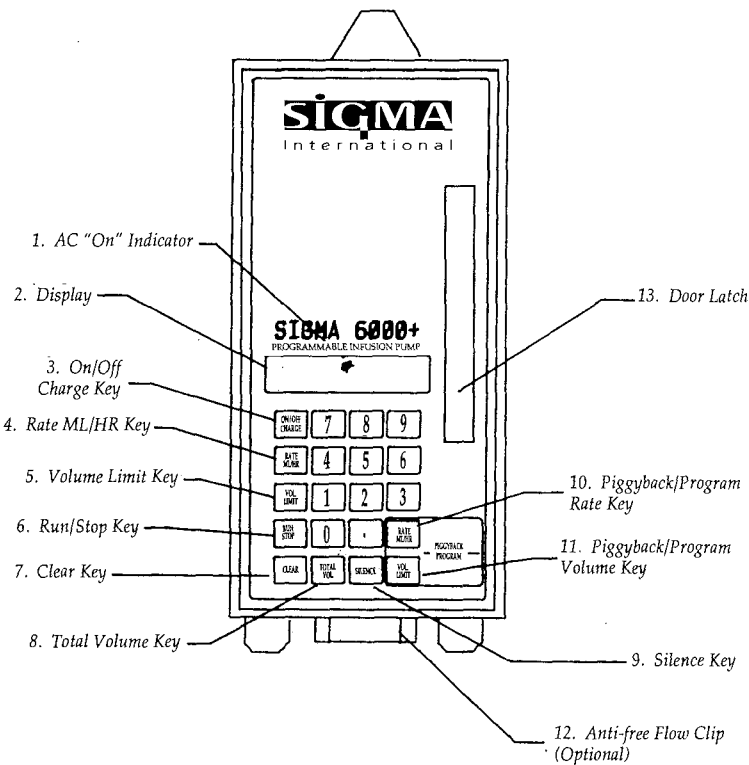
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Introduction

The SIGMA 6000+ Programmable Infusion Pump is designed to provide accurate and reliable administration of intravenous drugs and fluids. The pump's infusion rate is selectable from 0.1 ml/hr to 999 ml/hr. The pump utilizes standard low cost Abbott, Baxter or McGaw* micro and macro drip administration sets (as well as several European set brands). To ensure safety and ease of operation, the 6000+ has a user prompting system and a full range of diagnostic alarms.

PLEASE READ AND UNDERSTAND THIS ENTIRE OPERATOR'S MANUAL BEFORE USING THE PUMP AND RETAIN IT FOR FUTURE REFERENCE.

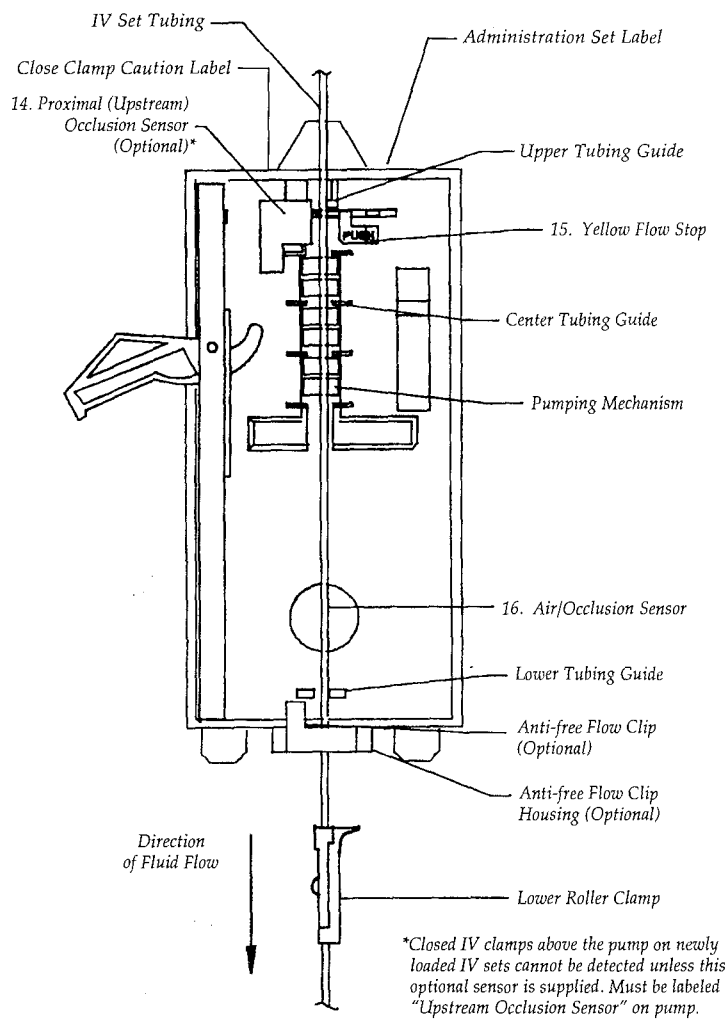*Abbott, Baxter, and McGaw are registered trademarks. Contact SIGMA for a complete list of compatible IV sets.

Diagram – Front View
(door closed)

1. AC "On" Indicator
2. Display
3. On/Off Charge Key
4. Rate ML/HR Key
5. Volume Limit Key
6. Run/Stop Key
7. Clear Key
8. Total Volume Key

13. Door Latch
10. Piggyback/Program Rate Key
11. Piggyback/Program Volume Key
9. Silence Key
12. Anti-free Flow Clip (Optional)

Operating Controls

1. Indicates pump is plugged in to AC power (battery will charge).
2. LED Digital Display.
3. Power Key. Turns pump on and off (battery charges in either mode).
4. Sets infusion rate in milliliters per hour.
5. Sets volume (ml) of solution to be infused.
6. Starts and stops the infusion pump.
7. Clears any or all values.
8. Counts milliliters infused.
9. Stops alarm from sounding for 2 minutes.
10. Sets the rate for automatic piggybacking and programming.
11. Sets the volume for automatic piggybacking and programming.
12. May prevent accidental free flow when set is removed from pump (optional).
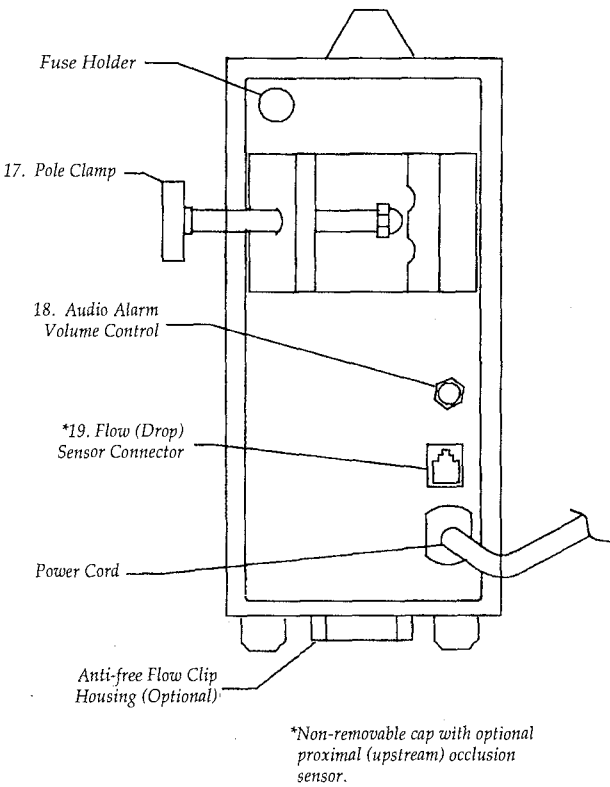13. Opens and closes door.

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Diagram – Front View
(door open)

IV Set Tubing ———

Close Clamp Caution Label ——

14. Proximal (Upstream)
Occlusion Sensor
(Optional)*

——— Administration Set Label

——— Upper Tubing Guide

——— 15. Yellow Flow Stop

——— Center Tubing Guide

——— Pumping Mechanism

——— 16. Air/Occlusion Sensor

——— Lower Tubing Guide

——— Anti-free Flow Clip
(Optional)

——— Anti-free Flow Clip
Housing (Optional)

Direction
of Fluid Flow

——— Lower Roller Clamp

*Closed IV clamps above the pump on newly
loaded IV sets cannot be detected unless this
optional sensor is supplied. Must be labeled
"Upstream Occlusion Sensor" on pump.

Operating Controls (continued)

14. Detects closed IV clamps above the pump on newly loaded IV sets (optional).
15. Prevents free flow of IV fluid when door is opened.
16. Detects air bubbles, and occlusions below the pump.

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Diagram – Rear View

Fuse Holder

17. Pole Clamp

18. Audio Alarm
Volume Control

*19. Flow (Drop)
Sensor Connector

Power Cord

Anti-free Flow Clip
Housing (Optional)

*Non-removable cap with optional
proximal (upstream) occlusion
sensor.

Operating Controls (continued)

17. Attaches pump to IV pole.
18. Varies the volume of the audio alarm.
19. Receptacle for optional flow (drop) sensor.

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Instructions
For Use

1. Select specified IV sets only (see top of pump) and prime.
2. Open pump door, push in yellow flow stop, pull anti-free flow clip out (optional), load its retractor cord in slot on left side of clip housing.
3. Load set straight between and fully into all tubing guides, place anti-free flow clip over tubing and load it into its housing (locate roller clamp below pump).
4. Close pump door.
5. Open all set clamps. Confirm no drip flow.
6. Press ON. Observe all 8's in display.
7. Press RATE (ml/hr). Within 5 seconds, use numerical keyboard to set rate.
8. Press VOL. LIMIT. Within 5 seconds, use numerical keyboard to set volume limit.
9. Press RUN to start infusion. RATE will scroll.
10. Be sure drip chamber flow approximates RATE and all settings are as desired.
11. To make changes, press STOP, then desired key, change value with keyboard, press RUN.
12. Press TOTAL VOL to display total vol. infused. To clear, press STOP, TOTAL VOL., then CLEAR.
13. For KEYLOCK see page 6.
14. To avoid nuisance alarms: reload fresh, unpumped on tubing in front of AIR/OCCL SENSOR and optional proximal (upstream) occlusion sensor, fully insert tubing into flow stop and proximal (upstream) occlusion sensor. Warm solutions to room temperature (cold solutions are the primary cause of micro bubbles), fill drip chamber halfway, remove air from IV bags and Y-sites, use only specified IV sets, keep AIR/OCCL SENSOR and anti-free flow clip clean/dry, and invert (do not shake) bags when mixing solutions.

Addendum to SIGMA 6000+ Operator's Manual Rev. B - 85601

Additional Instruction For Use: Pg. 5; Step 3

IMPORTANT: The section of the administration set to be placed in the SIGMA Pump is that section where the main roller clamp is located.

Keylock
Operation

Prevents unauthorized tampering with front panel key pads.

1. To engage KEY LOCK, enter RATE and VOL. LIMIT, press RUN to start infusion and within 30 seconds press decimal point (.) twice.

   • While key lock is engaged, all parameters (Rate, Vol. Limit, Total Vol.) keys are active to allow routine infusion data checks.

   • When operator attempts to stop pump while key lock is engaged, display will read KEY LOCK, then resumes scrolling RATE.

   • In an emergency, the pump can be stopped by opening the door.

2. To disengage Key Lock, press decimal point twice within 2 seconds. NO LOCK displays, then the scrolling RATE resumes.

Alarms and
Troubleshooting Tips

1. NUISANCE ALARMS: See #14 under INSTRUCTIONS (page 5).

2. AUDIO: Press SILENCE to override audio alarm for 2 min. Adjust loudness on back panel of pump.

3. INACCURATE RATE: Have pump tested, use IV set in question, pump into a graduate or pipette.

4. DROPPED OR DAMAGED PUMPS: Do not use until calibration is checked.

5. CLR AIR: See #14 under INSTRUCTIONS (page 5).

   • Press RUN to clear small bubbles.

   • To purge large bubbles out of lower Y-site, open door, open flow stop, push and hold in anti-free flow clip (optional) to create gravity flow.

6. CHK TUBE/CLR AIR: Load tubing in front of AIR/OCCL SENSOR.

Alarms and Troubleshooting Tips (continued)

7. CLR OCCL: See #14 under INSTRUCTIONS (page 5)

   Check for positional IV, closed clamps, kinked tubing, clogged filter, clotted catheter, then press RUN.

8. PROX OCCL/EMPT BOTT: (Optional with flow sensor). Proximal (upstream) occlusion or empty IV bag. Correct, press run.

9. PROX OCCL: (optional with proximal (upstream occlusion sensor). IV clamp above the pump on newly loaded set is closed. Open clamp, press RUN.

10. INF COMP: Infusion complete, press STOP (halts KVO), set new VOL. LIMIT, press RUN (container overfill accounts for fluid residuals).

11. PROG COMP: Ramping/tapering program is complete. Press STOP (halts KVO), then press OFF.

    At next press of ON, pump recycles program and starts over with prior RT 1, VL1.

12. TIME OUT: Pump is in program (ramping) mode, has been left in STOP for 30 min., pump has recycled to RT 1, VL 1.

13. LOAD CLIP/SHUT DOOR: Load anti-free flow clip (optional) into its housing and fully close door.

14. BATT ON: Pump running on battery.

    LOW BATT: Approximately 30 min. life remains.

    PLUG IN: Battery depleted, plug pump in, push RUN (plug pump in when not in use).

15. H/L RATE, PUMP FAIL, MULT FAIL, BAD RAM: Pump malfunctions. Press RUN to restart pump. If alarm continues, remove from service.

16. KEYLOCK: (See operators manual page 6).

17. RATE ERR/VOL ERR: RATE or VOL. LIMIT setting exceeds maximum setting.

18. PUSH RUN: Pump has been stopped 2 min.

19. FLOW SNSR: Flow (drop) sensor must be attached to drip chamber to start pump.

20. ANTI-FREE FLOW CLIP (optional): After set removal from clip, place clip back into holder. Do not allow to snap back into holder (clip can be damaged).

21. IN STOP/PUSH RUN: Pump operation stopped. Push RUN to restart.

Piggybacking – Automatic

1. Use only compatible back check valve primary (specified on top of pump), and secondary piggyback sets.

2. Select primary RATE and VOL. LIMIT before setting secondary piggyback values.

3. Prepare and attach secondary piggyback container and set to upper Y-site of primary back check valve set.

4. Lower primary container below secondary piggyback using hanger provided with secondary set.

5. With pump stopped, press and set piggyback RATE and VOL. LIMIT keys (found on right side of keyboard).

6. Open all clamps. Press RUN to start infusion.

7. Assuming pig. VOL. LIMIT equals actual pig. container volume, gravity switchover from pig. to primary container will coincide with pumps switchover from piggyback to primary settings (4 audio tones will occur).

Programming (ramping/tapering)

Enables up to 12 successive rates and volume limits to be entered.

1. Follow steps 1-5 under INSTRUCTIONS (page 5 in manual). Then press ON and clear all keyboard values (see #9).

2. Press and hold program RATE (right side of keyboard) until PROG MODE appears (not PIG MODE).

3. Press PROG RATE, set RT 1.

4. Press PROG VOL. LIMIT, set VL 1.

5. Repeat steps 3 and 4 for the PROG RATES and VOLUME LIMITS desired (RT 2 will appear next).

6. To review all program settings, press PROG RATE once (RT 1 displays), then press PROG VOL (VL 1 displays), then press PROG RATE twice to review subsequent rates and volume limits.

7. Press RUN to start infusion, or OFF to save the program indefinitely in the pumps memory.

8. Pump will go through the RATE and VOLUME LIMIT sequence programmed, concluding with a PROG COMP alarm (see ALARMS).

9. To clear entire program and TOTAL VOL., turn pump OFF, then ON – while pressing CLEAR for 7 seconds.

Flow (drop) Sensor Use (optional)

Flow sensor attaches to IV set drip chamber and detects upstream occlusions or empty IV bags.

1. Plug sensor cord into back of pump.

2. Attach sensor to IV set drip chamber, with sensor arrow midway between drop orifice and drip chamber fluid level.

3. Avoid nuisance alarms by: filling drip chamber no more than half full, turning the sensor opening away from sunlight, avoiding sensor shaking or tilting, and by using macro drop sets above 200 ml/hr.

4. When using a flow sensor in the piggyback mode, place the flow sensor on the primary set drip chamber.

   The pump will alarm "PROX OCCL, EMPT BOTT" if:

   1) Drops are detected in the primary IV set before the PIG Volume Limit has infused.

   2) The PIG Volume Limit has counted down to zero and solution overfill in the piggyback container continues to infuse at the primary rate.

Cleaning Pumps

1. Disconnect power plug from AC power source before cleaning.

2. Clean exterior surfaces with pump in upright position. Apply cleaners with a dampened cloth per manufacturers' instruction and dilution ratios. Subsequent disinfection is recommended using the same application technique. Disinfects should remain on the pump surface in an even, but not dripping, film for the manufacturers' recommended contact time. Wipe dry or air dry after completion of contact time period before pump reuse. Dispose of all cleaning/disinfectant materials per federal, state and local regulations for infectious waste disposal.

   DO NOT – spray, sterilize by autoclaving or ETO gas, or immerse any part of the pump.

   Extended use of phenolic based cleaners or disinfectants may cause damage to the membrane keypad.

   The following cleaners and disinfectants may be used.

   - 70% to 90% ethyl or isopropyl alcohol in water.[1]
   - 10% bleach in water (produces 0.55% Sodium Hypochlorite) or a Sodium Hypochlorite cleaner disinfectant such as:
     Dispatch®[2] by Caltech Industries, Inc. 1-800-234-7700
   - Quaternary based germicidal detergent such as:
     T.B.Q.®[2] by Calgon Vestal Laboratories 1-800-325-8005
     HI-TOR PLUS®[2] by Huntington Laboratories, Inc. 1-800-448-6522
     SANI-TURGE®[2] 256 by Purex Industrial, Corp. 1-800-848-4901

• Cleaning Flow (drop) Sensors: Clean flow (drop) sensor and pump flow sensor connector with a small amount of isopropyl alcohol and a cotton swab. **Use of electrical contact cleaners will cause damage to these parts.**

NOTES:
1. Alcohols are flammable and should be used in a well-ventilated area.
2. The selection and use of disinfectants should be in accordance with hospital and user facility policies. This listing is strictly provided to indicate pump material compatibility with cleaning and disinfectant agents.

Servicing Pumps

CAUTION: Electric shock hazard. No user serviceable parts.

1. Refer faulty pumps to in-house trained service technicians. Refer to Service Manual for pump inspection and preventative maintenance procedures.
2. When pump return to SIGMA is desired:
   • Phone 1-800-356-3454 for a repair authorization (RA) number. This requires a P.O. no. for non-warranty repairs.
   • Ship pump to SIGMA at:
     11020 West Center Street Extension, Medina, NY 14103 (return in original box)
   • Include a problem description, a contact person, phone number, return address and label the shipping box with the RA number.
3. Required Maintenance and Frequency:
   • Maintenance consists of operational evaluation in accordance with the procedures for Test Mode and Flow Rate Accuracy as described in the service manual. It is recommended this evaluation be performed within a minimum interval of twelve (12) months.
4. Battery use and Maintenance:
   • If LOW BATT display is seen upon start, battery is insufficiently charged. To recharge battery, plug supply cord into an outlet for 18-24 hours. Recharge is automatic and can be done while pump is operating.
   • If left idle for long periods of time (3 months or more) unit should be plugged into AC outlet to recharge.
   • Batteries are maintenance free and should last a minimum of 200 full discharge/charge cycles.
5. Protective Grounding:
   • When the integrity of the protective earth conducter is in doubt, this equipment should be operated from the internal battery source by disconnecting it from the AC power source.

Cautions

1. Operation of this pump is restricted to trained users who have a complete understanding of these instructions and standard IV therapy practices.

WARNING

⚠ **This symbol has been placed on the pump to indicate potentially hazardous situations and the need for full user understanding.**

2. Use only specified IV sets (see top of pump), or inaccurate flow rates and false alarms result.

3. a) Close roller clamp before set removal from flow stop and anti-free flow clip (optional) or free flow results.

   b) To remove set from anti-free flow clip:
      1) Close roller clamp
      2) Pull tubing straight out from the underside of the clip.

4. To create gravity flow, close the sets roller clamp, open the pump door, open flow stop, push and hold in the anti-free flow clip (optional feature), and control gravity flow with roller clamp adjustment.

5. Pumps not equipped with the optional flow (drop) sensor, or the optional proximal (upstream) occlusion sensor, can not detect closed clamps above the pump.

6. For pumps equipped with the optional proximal (upstream) occlusion, at rates below 5ml/hr, times to occlusion are extended and not clinically effective.

7. Infiltrations can not be detected. They must be observed and minimized by operators.

8. DANGER – possible explosion hazard when used in the presence of flammable anesthetics. Risque d'explosion. Ne pas employer en presence d'anesthesiques inflammables.

9. CAUTION: Electric shock hazard. No user serviceable parts. Do not remove case. Refer servicing to qualified service personnel.

   ⚠ This symbol is a warning to replace fuse as marked.

10. Federal (USA) law restricts this device to sale by or on the order of a physician or other licensed practitioner.

11. For pumps that are dropped or damaged, always have calibration checked to prevent flow rate errors.

Limited Warranty

SIGMA warrants, to the original purchaser, the SIGMA 6000+ Programmable Infusion Pump (hereinafter pump) to be free from defects in material and workmanship under normal use and service for one year from the date of purchase. SIGMA's obligation under this limited warranty shall be limited to repair or replacement of pumps which, upon SIGMA's examination, are found defective in material or workmanship under normal use and service within one year from the date of purchase by the original purchaser. The repair or replacement of any pump under this limited warranty shall not extend the term of this limited warranty beyond the original term as set forth in this paragraph.

All repairs qualifying under this limited warranty must be performed by qualified, trained service personnel. In the event that any pump is found to be defective during the aforesaid warranty period, the purchaser shall notify SIGMA in writing of any claimed defect within thirty days after such claimed defect is discovered. The pump claimed to be defective must then be promptly delivered to SIGMA or its designated representative for inspection and repair or replacement, if necessary. Pumps returned to SIGMA must be properly packaged and sent to SIGMA with postage and handling prepaid. Severe pump damage may result if SIGMA shipping cartons and inserts are not used. Shipping cartons and inserts are available at no charge from SIGMA.

This limited warranty shall not apply to defective conditions or damage caused, in whole or in part, by negligence, fluid spills, dropped pumps, misuse, abuse, improper installation, improper cleaning, alteration, or damage resulting from improper shipment to SIGMA. If, after inspection, SIGMA is unable to identify a problem, SIGMA reserves the right to invoice purchaser for such inspection.

THIS LIMITED WARRANTY IS THE SOLE AND ENTIRE WARRANTY PERTAINING TO THE PUMP AND IS IN LIEU OF AND EXCLUDES ALL OTHER WARRANTIES OF ANY NATURE WHATSOEVER WHETHER EXPRESS, IMPLIED OR ARISING BY OPERATION OF LAW, TRADE, USAGE OR COURSE OF DEALING, INCLUDING, BUT NOT LIMITED TO, WARRANTIES OF MERCHANTABILITY OR FITNESS FOR ANY PARTICULAR PURPOSE. ANY AFFIRMATION OF FACT OR PROMISE MADE BY SIGMA SHALL NOT BE DEEMED TO CREATE AN EXPRESS WARRANTY THAT THE PUMP SHALL CONFORM TO THE AFFIRMATION OR PROMISE; ANY DESCRIPTION OF THE PUMP IS FOR THE SOLE PURPOSE OF IDENTIFYING IT AND SHALL NOT BE DEEMED TO CREATE AN EXPRESS WARRANTY THAT THE PUMP SHALL CONFORM TO SUCH DESCRIPTION; ANY SAMPLE OR MODEL IS FOR ILLUSTRATIVE PURPOSES ONLY AND SHALL NOT BE DEEMED TO CREATE AN EXPRESS WARRANTY THAT THE PUMP SHALL CONFORM TO THE SAMPLE OR MODEL; AND NO AFFIRMATION, PROMISE, DESCRIPTION, SAMPLE OR MODEL SHALL BE DEEMED TO BE PART OF THE PURCHASE OF THE PUMP. PURCHASER EXPRESSLY ACKNOWLEDGES THAT THIS LIMITED WARRANTY CONSTITUTES PURCHASER'S SOLE AND EXCLUSIVE REMEDY WITH RESPECT TO ANY CLAIM OF PURCHASER ARISING OR RESULTING DIRECTLY OR INDIRECTLY FROM THE USE OF THE PUMP. IN NO EVENT SHALL SIGMA BE LIABLE HEREUNDER FOR AN AMOUNT WHICH EXCEEDS THE PURCHASE PRICE OF THE PUMP. NO PERSON, FIRM OR CORPORATION IS AUTHORIZED TO ASSUME FOR SIGMA ANY LIABILITY IN CONNECTION WITH THE SALE OF THE PUMP.

Specifications

Operating Principle
Linear peristaltic

Rate Range
0.1-999 ml/hr

Accuracy
±5% (2-999 ml/hr)
±0.1 ml (0.1-2.0 ml/hr)

Volume Limit Range
0.1-9999 ml

KVO Rate
1 ml/hr or selected rate, whichever is less

Administration Set
Standard administration sets
(Abbott, Baxter or McGaw** and several European Sets)

Alarms
Air: (>0.1 ml) • Distal (downstream) Occlusion (11 ± 7 PSI), Proximal (upstream)
Occlusion (optional) – detects closed clamps on newly loaded IV sets
Open Door • Infusion Complete
Program Complete • Piggyback Complete
Low Battery/Plug In • Malfunctions
Empty Container (with optional flow sensor)

Anti-Free Flow Protection
Primary: 2 step actuated "hooked" flow stop
Redundant: 3 step actuated "anti-free flow" clip (optional)

Power Requirements
105-135 volts AC, 50/60 Hz – U.S.
220/240 volts AC, 50/60 Hz, 20w. – European

Grounding Resistance
<0.1 ohm

Electrical Leakage
<15 micro amps

Battery Operation – 12 Volt sealed rechargable, 3.2 Ampere-hour Rating
Approx. 6 hours on fully charged new battery
(5 hrs. with optional proximal occlusion circuit)
18 hour charge time

Dimensions
9.75" H x 4" W x 9.5" D
(248 mm x 102 mm x 241 mm)

Weight
11.1 lbs. (5.0 kg)

UL Listed/CSA Certified
** Abbott, Baxter and McGaw are registered trademarks.
Contact SIGMA for complete list of compatible sets.

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SIGMA
International

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716-798-3901 or 1-800-356-3454 • Fax: 716-798-3909

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